

mailing address in §600.2(a) of this chapter).

(v) *Dead animals.* Dead animals may be used as source material in the manufacture of Allergenic Products: *Provided*, That (a) the carcasses shall be frozen or kept cold until the allergen can be collected, or shall be stored under other acceptable conditions so that the postmortal decomposition processes do not adversely affect the allergen, and (b) when alive, the animal met the applicable requirements prescribed in paragraphs (b)(3) (i), (ii), and (iii) of this section.

(vi) *Mammals and birds inspected by the U.S. Department of Agriculture.* Mammals and birds, subject to inspection by the U.S. Department of Agriculture at the time of slaughter and found suitable as food, may be used as a source material, and the requirements of paragraph (b)(3) (i) through (iv) of this section do not apply in such a case. Notwithstanding U.S. Department of Agriculture inspection, the carcasses of such inspected animals shall be frozen or kept cold until the allergen is collected, or shall be stored under other acceptable conditions so that the postmortal decomposition processes do not adversely affect the allergen.

(c) *Listing of source materials and suppliers.* Each licensed manufacturer shall initially list with the Director, Center for Biologics Evaluation and Research (see mailing address in §600.2(a) of this chapter), the name and address of each of the manufacturer's source material suppliers. The listing shall identify each source material obtained from each source material supplier. The licensed manufacturers shall update the listing annually to include new source material suppliers or to delete those no longer supplying source materials.

(d) *Exemptions.* (1) Exemptions or modifications from the requirements under paragraph (b) of this section shall be made only upon written approval by the Director, Center for Biologics Evaluation and Research.

(2) Nonlicensed source material suppliers are exempt from drug registration.

[38 FR 32100, Nov. 20, 1973, as amended at 49 FR 25432, June 21, 1984; 49 FR 31395, Aug. 7, 1984; 55 FR 11014, Mar. 26, 1990; 67 FR 9587, Mar. 4, 2002; 70 FR 14986, Mar. 24, 2005; 80 FR 18093, Apr. 3, 2015]

§ 680.2 Manufacture of Allergenic Products.

(a) *Extraneous allergenic substances.* All manufacturing steps shall be performed so as to insure that the product will contain only the allergenic and other substances intended to be included in the final product.

(b) *Cultures derived from microorganisms.* Culture media into which organisms are inoculated for the manufacture of Allergenic Products shall contain no allergenic substances other than those necessary as a growth requirement. Neither horse protein nor any allergenic derivative of horse protein shall be used in culture media.

(c) *Liquid products for oral administration.* Liquid products intended for oral administration that are filled in multiple dose final containers shall contain a preservative in a concentration adequate to inhibit microbial growth.

(d) *Residual pyridine.* Products for which pyridine is used in manufacturing shall have no more residual pyridine in the final product than 25 micrograms per milliliter.

(e) [Reserved]

(f) *Records.* A record of the history of the manufacture or propagation of each lot of source material intended for manufacture of final Allergenic Products shall be available at the establishment of the manufacturer of the source material, as required by §211.188 of this chapter. A summary of the history of the manufacture or propagation of the source material shall be available at the establishment of the manufacturer of the final product.

[38 FR 32100, Nov. 20, 1973, as amended at 49 FR 25433, June 21, 1984; 67 FR 9587, Mar. 4, 2002]

§ 680.3 Tests.

(a) *Identity.* When a specific identity test meeting the provisions of §610.14 of this chapter cannot be performed, the

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manufacture of each lot shall be separated from the manufacture of other products in a manner that will preclude adulteration, and records made in the course of manufacture shall be in sufficient detail to verify the identity of the product.

(b) [Reserved]

(c) *Sterility*. A sterility test shall be performed on each lot of each Allergenic Product as required by § 610.12 of this chapter.

(d) [Reserved]

(e) *Potency*. The potency of each lot of each Allergenic Product shall be determined as prescribed in § 610.10 of this chapter. Except as provided in this section, the potency test methods shall measure the allergenic activity of the

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product. Until manufacturers are notified by the Director, Center for Biologics Evaluation and Research, of the existence of a potency test that measures the allergenic activity of an allergenic product, manufacturers may continue to use unstandardized potency designations.

(f) *Records*. The records related to the testing requirements of this section shall be prepared and maintained as required by §§ 211.165, 211.167, 211.188, and 211.194 of this chapter.

[38 FR 32100, Nov. 20, 1973, as amended at 39 FR 19777, June 6, 1974; 41 FR 4015, Jan. 28, 1976; 52 FR 37607, Oct. 8, 1987; 55 FR 11013, Mar. 26, 1990; 67 FR 9587, Mar. 4, 2002; 77 FR 26175, May 3, 2012; 77 FR 30884, May 24, 2012; 80 FR 37974, July 2, 2015]